

In the Claims

Claim 1 (Currently amended): A method of screening for early cancer, comprising the steps of:

- (a) measuring the level of full-length human midkine, or a truncated form thereof that lacks the entire N-terminal domain disposed between Asp26 and Gly81, in a body fluid; and,
- (b) comparing the measured level obtained in step a) (a) to a control human midkine protein level of a healthy subject, ~~wherein an elevated measured level as compared to the control level indicates the presence of early cancer, wherein early cancer comprises cancer at stage 0 or stage I of the TNM classification; and~~
- (c) diagnosing the presence of early cancer, defined as stage 0 or stage I of the TNM classification, when the comparison of step b) (b) indicates that the measured level is elevated as compared to the control level.

Claim 2 (Original): The method according to claim 1, wherein the early cancer is gastric cancer.

Claim 3 (Original): The method according to claim 2, wherein the gastric cancer is at stage I.

Claim 4 (Original): The method according to claim 1, wherein the early cancer is hepatocellular carcinoma.

Claim 5 (Original): The method according to claim 4, wherein the hepatocellular carcinoma is at stage I.

Claim 6 (Original): The method according to claim 1, wherein the early cancer is lung cancer.

Claim 7 (Original): The method according to claim 6, wherein the lung cancer is at stage I.

Claim 8 (Original): The method according to claim 1, wherein the body fluid is serum or urine.

Claim 9 (Currently amended): A method of screening for early cancer comprising the steps of:

(a) contacting a body fluid with a pair of antibodies that specifically bind to full-length human midkine, or a truncated form thereof that lacks the entire N-terminal domain disposed between Asp26 and Gly81, in a body fluid, and;

(b) comparing the level of binding between the antibodies and human midkine of step (a) to a control binding level of a healthy subject, ~~wherein an elevated binding level as compared to the control level indicates the presence of early cancer, wherein early cancer comprises cancer at stage 0 or stage I of the TNM classification; and~~

(c) diagnosing the presence of early cancer, defined as stage 0 or stage I of the TNM classification, when the comparison of step b) (b) indicates that the measured level is elevated as compared to the control level.

Claim 10 (Withdrawn): A diagnostic agent for early cancer comprising an antibody that recognizes midkine, a fragment thereof, or both.

Claim 11 (Withdrawn): A kit for detecting early cancer in a biological sample, wherein (a) the kit comprises a container that holds an antibody that specifically binds to at least one epitope of midkine, a fragment thereof or both, and (b) the antibody determines the presence of midkine, a fragment thereof or both in the biological sample.

Claim 12 (Withdrawn): The kit according to claim 11, wherein the antibody is adsorbed onto a solid.

Claim 13 (Currently amended): A method for assessing cancer prognosis, comprising the steps of:

(a) measuring the level of full-length human midkine, or a truncated form thereof that lacks the entire N-terminal domain disposed between Asp26 and Gly81, in a body fluid both before and after tumor treatment, comparing the level measured after treatment to a level measured before treatment, and

(b) correlating a difference in the measured levels to cancer prognosis, wherein a reduction in the measured level after treatment is indicative of successful treatment and positive prognosis.

Claim 14 (Original): The method according to claim 13, wherein the cancer is gastric cancer, hepatocellular carcinoma, or lung cancer.

Claim 15 (Previously presented): The method according to claim 1, wherein human midkine levels are measured using a sandwich enzyme immunoassay that includes an avian anti-human midkine antibody.

Claim 16 (Previously presented): The method according to claim 13, wherein human midkine levels are measured using a sandwich enzyme immunoassay that includes an avian anti-human midkine antibody.